

Message

From: Welch, Kara [welch.kara@epa.gov]
Sent: 6/21/2021 7:26:52 PM
To: Striegel, Wiebke [Striegel.Wiebke@epa.gov]; Reynolds, Alan [Reynolds.Alan@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
CC: Weiner, Matthew [weiner.matthew@epa.gov]; Pierce, Amanda [pierce.amanda@epa.gov]; Kirk, Cassandra [kirk.cassandra@epa.gov]
Subject: RE: Oxitec EUP - an issue with the current releases

Hi team,

I don't think the section g will need to be changed. It includes very generic statements about larval diet such as the below:

- "Place the larval diet block and the water preservative in the Box"
- "At the prescribed release locations, in the case of egg releases prescribed amounts of water, mosquito food, and other additives will be added to Mosquito Rearing Boxes, as described in Volume 4 of this application"

Per Wiebke's comment, this sounds like the change to larval diet would affect the CSF and SOPs rather than the section g.

Thanks,
Kara

From: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Sent: Monday, June 21, 2021 3:24 PM
To: Reynolds, Alan <Reynolds.Alan@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Weiner, Matthew <weiner.matthew@epa.gov>; Pierce, Amanda <pierce.amanda@epa.gov>; Welch, Kara <welch.kara@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>
Subject: RE: Oxitec EUP - an issue with the current releases

Hello Alan,

I don't know about the section G, but these types of changes would likely require the company to provide a new CSF and a new volume of the SOPs. Based on your email, I would assume that a review of those changes would indeed mostly be administrative.

I just want to note that the company has currently an amendment in house to include CA and NV in their EUP. May be good to talk to them to ask if they want to include these changes in the larval diet for that amendment as well.

Wiebke

From: Reynolds, Alan <Reynolds.Alan@epa.gov>
Sent: Monday, June 21, 2021 3:07 PM
To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Weiner, Matthew <weiner.matthew@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Pierce, Amanda <pierce.amanda@epa.gov>; Welch, Kara <welch.kara@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>
Subject: Oxitec EUP - an issue with the current releases

Mike et al.-

I just got off the phone with Keith Matthews who gave me an update on the Oxitex EUP proceeding in Florida. Apparently, the male rearing/release boxes are not producing enough males, which is (for obvious reasons) adversely affecting the trials. Oxitec believes it's due to the diet they're currently using in the boxes. They have data from other trials in Brazil in which a different diet was used and adequate numbers of males were produced. To salvage the Florida trials, the company is going to propose to switch the diet in the rearing boxes to match the diet used in Brazil.

Keith wants to know the best way to make this change. My assumption is that the rearing box diet is specified in the Section G (Kara/Amanda – true?) and a formal amendment would be needed to change it. My second assumption is that the amendment would largely be an administrative change and would not need much of a science review (please correct me if I'm wrong). Keith/Oxitec are very concerned about the timing if the amendment process is long – they would like to avoid submitting it as a PRIA action if possible.

I told Keith we would get back in touch with him as soon as possible after we've had a chance to discuss internally.

Thanks, Alan

